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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,757	04/05/2006	David Parkinson	ON/4-33248A	1625
1095 7590 05/22/2008				
NOVARTIS				
CORPORATE INTELLECTUAL PROPERTY				
ONE HEALTH PLAZA 104/3				
EAST HANOVER, NJ 07936-1080				
EXAMINER				
WEBB, WALTER E				
ART UNIT		PAPER NUMBER		
1612				
MAIL DATE		DELIVERY MODE		
05/22/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/561,757

**Applicant(s)**

PARKINSON ET AL.

**Examiner**

WALTER E. WEBB

**Art Unit**

1612

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3-12, 25 and 28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-12, 25 and 28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicants' arguments, filed 2/11/2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 103***

The rejection of claims 1-41 under 35 USC 103(a) as being unpatentable over O'Reilly et al. in view of Williams et al. is maintained in regard to claims 1, 3-12, 25 and 28. Claims 2, 13-24, 26, 27, and 29-41 have been cancelled.

Applicant argues that it was important to establish a proper dosing schedule to optimize the effects of EPO906 while reducing the side effects of diarrhea. However, as presented previously, the adjustment of the amount of the compound to optimize desired results would be obvious to a person having ordinary skill in the art. The adjustment of EPO906 to decrease toxicity and side effects such as diarrhea are well within the purview of the artisan.

Applicant argues that it would not have been obvious to modify the calculated dose described in O'Reilly to administer the composition continuously for 6 to 24 hours,

because it was not known that EPO906 may have side effects associated with dosing. However, the dosing schedule of O'Reilly is a preferred embodiment, which means that dosages can vary. O'Reilly promotes infrequent administration stating that "it should reduce the frequency and duration of hospitalization . . . and less toxicity than more frequent treatments." (See col. 5, lines 43-54) O'Reilly is promoting efficacy here. And Williams provides an efficacious treatment of a 24 hour infusion as compared to shorter infusion times with a drug in the same class. Furthermore, applicant's claims are not limited to treatment of diarrhea, and the motivation for the adjustment supplied by Williams is deemed sufficient.

Applicant argues that the comparison of paclitaxel of Williams and Epithilone B is illogical. Applicant argues that they are two different therapeutic agents, with different chemical structures. However, both compounds treat the same types of cancer and are also members of the same class of cancer fighting agents, microtubule stabilizers. Applicant's attention should be drawn to Daiichi Sankyo v. Apotex, 84 USPQ2d 1285, 1288 (Fed. Cir. 2007), where the court found ofloxacin use for treating an ear infection to be obvious over use of another gyrase inhibitor, ciprofloxacin, for treating an ear infection. It would have been reasonable for the artisan to expect success in administering Epithilone B in the same manner as paclitaxel, especially since O'Reilly compares Epithilone B to paclitaxel pointing out that they share the same binding site. (See Background of the invention at col. 2, lines 54-67, and co. 3, lines 62-67.)

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 8:00am-4:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Walter E. Webb  
/Walter E Webb/  
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612